

Summary of Session with Centers for Medicare/Medicaid Services (CMS) Hosted by HL7 SPL ER/DL Team on April 27, 2011

Participants from CMS: Craig Miner, Rebecca DeCastro, Jessica Herrera-Cancel, Kady Flannery

CMS is responsible for administering the Medicare Part D statute related to drug reimbursement.

The statute contains a definition of drugs for reimbursement which meet the measures of safety and efficacy, and are within certain therapeutic categories. Still, it is not always easy to know which products/NDCs are reimbursable because FDA marketing categories may not be obvious (e.g. approved under NDA, ANDA, BLA vs. non-approved).

CMS would like to use the FDA's NDC Directory as the 'gold standard' for a drug being properly listed and having been approved or recognized by FDA in the US using measures of safety and efficacy. Thus, products on the NDC Directory can be considered actively marketed and eligible for reimbursement.

Challenges:

- Determining FDA marketing category of a drug product/NDC
- Knowing if a drug product/NDC is actively marketed
- Non-agreement/discrepancies between the NLM's RxNorm database, Orange Book and NDC Directory (both legacy system and E-listing)
- Many data sources with limited flexibility for searching and cross-matching information
- Lack of certain needed FDA approval information in NDC Directory, eg, if product is brand or generic
- Format of NDCs is 10 digits instead of widely used HIPAA 11-digit format
- Manufacturers don't always drug list inner package NDCs

Recommendations/Improvements:

- Use HIPAA 11-digit NDC format, and include date the NDC was added to or deleted from the FDA's NDC Directory
- Drug makers must ensure drugs are properly listed and delisted per FDA requirements and Medicare Coverage Gap Discount Program Manufacturer Agreements
- Define the 'market end date' as last lot expired used for delisting purposes
- Availability of real time updates to NDC Directory
- Eliminate legacy systems, and NDC Directory becomes single 'gold standard' source
- Include marketing category (brand vs. generic) in NDC Directory and ensure transparency if this status changes
- Retain delisted product information in a history rather than deleting and having the listing just 'disappear', and include cause for removal
- Increase checks of quality and accuracy of information in NDC Directory, i.e., to eliminate typos or incorrect information
- Allow a specific NDC to be assigned a 'market end date'
- Mechanism to identify when an NDC is changing vs. being discontinued
- Manufacturers should drug list inner package NDCs even if these NDCs are not considered a saleable unit
- Ensure kits have only 1 NDC for the unit instead of separate NDCs for the components

Meeting Minutes of SPL ER/DL Hosted Teleconference with Centers for Medicare/Medicaid Services (CMS)

April 27, 2011, 1:00 pm EDT

Participants from CMS: Craig Miner, Rebecca DeCastro, Jessica Herrera-Cancel, Kady Flannery

CMS is responsible for administering the US Medicare/Medicaid programs, including the Medicare Part D Program started in 2006.

CMS intends to use NDC Directory as the 'gold standard' resource for determining drug reimbursement eligibility under Part D. The Medicare Coverage Gap Discount program started in 2011, so an additional requirement is to know if a product is approved and whether it is approved as a brand or generic.

There is a definition of a Part D drug in Statute around measures of safety and efficacy, and that defines and limits what categories of drugs can be reimbursed, however, there are still challenges in making eligibility determinations. It has been challenging identifying which NDCs belong to which FDA marketing category.

There is an issue with knowing which NDCs in the NDC Directory represent currently marketed drugs on the market and which are no longer active. There are also discrepancies between the Orange Book and the review of the listings and it is unclear which is correct.

Additionally, CMS uses First DataBank, Medispan, RxNorm, the Orange book, and drugs@FDA as sources for information.

(For purpose of these teleconference minutes, the term manufacturer may be interchangeable with distributor/labeler)

Questions and Answers

Q: How does CMS interact with FDA?

A: CMS has ongoing conversations with Office of Compliance, and with Randy Levin's group. The goal is to be able to point to the NDC Directory as the 'gold standard' for identifying appropriately listed Part D eligible products.

Q: How does CMS utilize the NDC Directory, SPL posted on NLM DailyMed, and drug product listing information?

A: CMS would like to treat NDCs in the NDC Directory as correct and current and know that everything listed is an active product still on the market. Ideally, the list should inform CMS what to pay for, e.g., last lot expiration date has not yet passed. CMS doesn't want to pay claims for NDCs that aren't active or available anymore, and many old NDCs remain on the NDC Directory and FDA's legacy listing information. In addition the same NDC may be listed with more than one application number or application type.

The e-Listing at labels.fda.gov are a very useful way to get the NDC information, because the eList has more information (NDCs, Orange Book data, etc).

CMS would like to see NDCs in the HIPAA 11-digit standard, marketing end date, application number, marketing category, date it was added to the NDC directory. If a drug is listed as an NDA and determined by the Part D sponsor to be a Part D drug, the plan will get reimbursed for the manufacturer discount portion paid on this drug in the coverage gap. If a few months later, an NDC is now listed under an ANDA, it is difficult to track when & how this changed as well as the impact. CMS would also like to see changes to a marketing category, marketing start and end date. When NDCs/products are removed from the NDC directory [due to delisting], there's nothing for CMS to see 'when and why' of the removal, so CMS has been tracking removals internally since Jan 2011. Some of the data doesn't appear to have been normalized (QA'd and checked against Orange Book) and CMS would like normalization to occur.

CMS uses the DailyMed for the marketing end date (last lot expiry date), as expect that they shouldn't see claims for the product past the marketing end date.

Q: Does CMS leverage the same NDC Directory database that the public has access to, or is CMS able to view real time drug listing information updates? Is there any concern around elapsed time in between a drug listing submission and the NDC Directory being updated/published twice monthly? How often does CMS access the NDC directory for drug listing NDC information?

A: CMS uses what is made publicly available and updated twice a month (rather than real-time). CMS would prefer to have no lag time. CMS would like to see a date on which the NDC was added to the NDC Directory.

Also, it is noted that the QA process seems to have some errors (transposition of numbers) in the transfer from the eList process to the NDC Directory, and it is labor intensive to determine what is correct.

Q: We have noticed that the public NDC Directory only includes labeler and product codes without presentation/put-up codes (package size). Does CMS utilize NLM DailyMed or some other source of NDC information in conjunction with the NDC Directory to access full NDC codes?

A: CMS uses First DataBank and Medispan, along with NDC Directory, Orange Book, labels@fda.gov and drugs@fda.gov. Using certain search criteria (labeler code along with product code) nets full NDC codes, including product/put-up code.

Q: What is the CMS Non-matched list? How is the CMS Non-matched list determined? How often is the CMS Non-matched list updated? Does CMS foresee a need for continuing a Non-matched list ongoing?

A: FDA has taken a list of NDCs from the NLM database (RxNorm data) and compared against FDA databases. That list was provided to CMS as being a list that 'should be in the NDC directory', but does not include products that are on the market and should be listed, but are missing from the FDA and NLM datasets. Also, note there is a lag time between a new drug just on the market and when it is listed on NDC Directory. CMS may have no way of differentiating between a claim for a new drug that should be reimbursed (an NDC on the market but isn't listed yet) and a claim for an old/invalid drug (NDC for a drug that isn't on the market).

The Non-Match List prevents pharmacies from using NDCs that do not represent products that are actually being dispensed and also requires manufacturers to list products with the FDA that are on the market if they want it removed from the Non-matched list. The Non-Match List is only created once a year, in conjunction with the FDA. There will likely be another Non-Match List in 2012.

Note: information about RxNorm can be found here: <http://www.nlm.nih.gov/research/umls/rxnorm/>
RxNorm is NLM's standardized nomenclature for clinical drugs and drug delivery devices that is linked to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. If one wants to find a specific data source for a specific listing, check RxNorm.

Q: Are there any CMS external guidelines or recommendations around product NDC assignments?

A: No, other than FDA's Food, Drug & Cosmetic Act requirements. CMS does not have any involvement in assigning NDCs.

Q: Are there any CMS needs for NDC codes that are not satisfied by current NDC drug listing procedures? Are there any CMS requirements that go beyond NDC drug listing, i.e., Sponsor-determined saleable units which are assigned NDC codes vs. single units of use?

CMS would like the NDC Directory to reflect:

1) the 11 digit NDC presentation (rather than the 10 digit)

- 2) inactive NDCs with the market end date/date of expiry of the last lot. This history would make it easier to process claims and understand issues. It is frustrating to see things disappear from the directory without knowing the reason.
- 3) date an NDC was added
- 4) inner package NDCs listed. CMS encounters issues with inner pack vs outer pack NDCs. CMS see claims for inner pack NDCs that are not necessarily drug listed and may contact manufacturers directly.
- 5) only the NDCs for the outer package of a co packaged kit.
- 6) all marketing products should be listed with an accurate FDA marketing category

Q: It's my understanding CMS submits a file to the FDA containing NDCs for verification against the FDA Directory. Can CMS review the source of these NDCs? Additionally, could CMS provide some insight as to how NDCs that had been discontinued greater than 5 years ago could appear on the Non-matched List? All expiration dates have passed and no product would be available.

A: CMS doesn't send a list to the FDA and have them compared. Instead the FDA does a compare between the RxNorm data and NDC Directory data, and sends the resulting list to CMS. It is the manufacturers' responsibility to submit accurate information and timely updates.

Q: Medicare Coverage Gap Discount Program Manufacturer Agreement – What percentage of companies have or have not complied with drug listing requirements?

A: Every company that signed the agreement commits to electronically list and keep the data correct. CMS doesn't know a compliance percentage, but have reached out for information on thousands of NDCs to Sponsors by going to the pharmacy databases and making sure they know if NDCs are obsolete, and to remove them. Thousands of NDCs may not be listed, or may be incorrectly listed.

One of the information sources that you could look at is the OIG report (2008 or 2009) on Part D claims (to the Medicaid program) for terminated NDCs.

Q: How long should we leave the NDC active past the market end date -- ie in order to make sure that the NDC is available for processing claims that come in after the market end date?

A: Have the SPL include the market end date. There should be no claims (date of service) for product past the last lot expiry date. CMS is looking into how much time they should allow for claims after last lot expiration, but 1 year is common.

Some other points from CMS:

- Some of the drug manufacturers are replacing NDCs (one product being replaced with another NDC) and it is unclear that it's the same identical product. It would be helpful to have a way to denote in the SPL/drug listing process (with a market start and end date) that clearly identifies that it's just a change to the NDC (like a labeler code change).
- There are ongoing discussions with FDA around levels of information to be included within SPL.
- It would be nice if the FDA would retire the legacy system and finalize the migration into a single source of NDCs. Possible there will be some updates on June 1.
- Resolve disagreements on application status between the Orange Book, Drugs@FDA, NDC directory and NLM Dailymed.

- The same NDC code may show up with two labeler codes and CMS is unable to determine when/how/why this happens.
- Would be very useful to have the market end date on each specific NDC package size presentation.

Sponsors are encouraged to work with the FDA to remove old records from the NDC Directory.